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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/683,537	10/09/2003	Todd Allen Berg	293/034 Div2	2610
1473	7590	06/10/2004	EXAMINER	
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			SNOW, BRUCE EDWARD	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 06/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/683,537	BERG ET AL.	
	Examiner	Art Unit	
	Bruce E Snow	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 40-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 50 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Different length finger from an end is not supported in the original specification.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 40, 42-44, 46-49, 52, 53, 55, and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Sachdeva et al (5,885,258).

Referring to all figures, specifically figures 8 and 9C, Sachdeva et al teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion; a plurality of resilient fingers 98 integral with the medial tubular portion and radially out from an axial end of and the medial tubular portion; and a plugging structure 99 substantially occluding the medial tubular portion.

Regarding the delivery structure, see at least element 93.

Regarding the elastic web, see column 5, lines 49-50.

Regarding pointed tip, see figure 8 which is also is interpreted as varying width.

Claims 40-44, 46-49, 51, 54-55 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Simon (5,741,297).

Simon teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion 34; a plurality of resilient nitinol fingers 12 integral with the medial tubular portion and radially out from an axial end of and the

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medial tubular portion; and a plugging structure substantially occluding the medial tubular portion.

Regarding claim 51, see figure 2, it is believed the device is fully capable of the free ends of the fingers overlapping when not implanted.

Claim 55, see tether 150 and loop end 36.

Claims 40-45, 47-49 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Huebsch et al (5,853,422).

Huebsch et al teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion 18; a plurality of resilient nitinol fingers 22 integral with the medial tubular portion and radially out from an axial end of and the medial tubular portion; and a plugging structure substantially occluding the medial tubular portion (see at least figure 6). Note the

Note barbs 70.

Regarding the web, see column 4, lines 25-27.

Claims 40, 42-43, 46-49, 55-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Lock et al (5,709,707).

Lock et al teaches a plug for use in plugging an aperture through a patient's body structure comprising: a medial tubular portion (see at least element 52 of Figure 7); a plurality of resilient fingers (arms including elements 26, 36 etc.) integral with the medial tubular portion and radially out from an axial end of and the medial tubular portion; and

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a plugging structure substantially occluding the medial tubular portion (see at least figure 7).

Regarding claim 55, see the coils structures best shown in figures 7 and 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva et al (5,885,258).

Sachdeva et al teaches the plug as described above and teaches a memory metal tube with is temperature activated, however, fails to teach nitinol. It would have been obvious to one having ordinary skill in the prosthetic arts to use nitinol because of these properties and biocompatibility. Silicone is also well known in the art as an elastic polymer (taught by Sachdeva et al) and would have been obvious to one having ordinary skill in the art to have used it for its biocompatibility.

Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon (5,741,297).

Simon teaches the plug as described above and teaches an elastic web however, fails to teach silicone. Silicone is also well known in the art as an elastic

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polymer and would have been obvious to one having ordinary skill in the art to have used it for the elastic web of Simon its elasticity and biocompatibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes

A handwritten signature in black ink, appearing to read 'B. Snow', with a long horizontal line extending to the right.

BRUCE SNOW
PRIMARY EXAMINER